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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,538	02/18/2004	Jerrold Rosenbaum	00786/376003	2440

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,538	ROSENBAUM, JERROLD	
	Examiner	Art Unit	
	Gregg Polansky	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-30 are pending.

2. Claims 1-30 are rejected.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caine et al, in view of Kutter et al (abstract of EP 417637) and US 6001861.

The claims recite a method for treating a human with a stimulant (cocaine) dependency, which may involve craving, with the administration of pramipexole (a dopamine agonist), in a dose range of 1.5 mg/day to 6.0 mg/day.

Caine et al. teach that pramipexole and other dopamine agonists decrease the self-administration of cocaine in rats. The Caine et al. reference is directed toward the treatment of human cocaine abuse. Indeed, they cite others who show "clinical utility in the management of cocaine abuse". Caine et al., do not teach the dose range of the instant invention.

Kutter et al teach the use of dopamine agonists (including pramipexole) for the treatment of drug dependency (which includes cocaine). They also teach a dose range

of 2.5 to 350 µg/kg (see abstract and EP 417637 page 9-12), which in a 50 kg individual would be a dose of 0.125 to 17.5 mg. Furthermore, '861 teach a dose range of pramipexole of 0.01 to 6 mg/day with a preferred range of 0.75 to 4.5 mg/day, stating that the dose should be titrated to achieve a maximal therapeutic effect.

The instant invention teaches a dose of 1.5 to 6.0 mg/day, it also teaches in the specification that "the invention is administered at a dosage appropriate to the effect to be achieved", and "the exact dosage of the compound may be dependent, for example, upon the age and weight of the recipient, the route of administration, and the severity and nature of the symptoms to be treated...without producing significant toxic or undesirable side effects". Both Kutter et al and '861 teach a dose range that encompasses the dose range of the instant invention and '861 further specifies the need to titrate the dose to achieve a maximal therapeutic effect. It would be obvious, to one of ordinary skill in the art, to combine these teachings to easily arrive at the same dosage as taught in the instant invention.

Therefore, to one of ordinary skill in the art, the above-cited references taken as a whole provide motivation to use pramipexole in the treatment of stimulant/cocaine craving, titrated to an effective dose within the dose range suggested in the instant invention.

5. Claims 7-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Caine et al, in view of Kutter et al (abstract of EP 417637) and US 6001861, further in view of WO 97/30977.

The claims recite a method for treating a human with a stimulant (cocaine) dependency, which may involve craving, with the intranasal administration of pramipexole (a dopamine agonist), in a dose range of 1.5 mg/day to 6.0 mg/day.

The teachings of Caine et al, in view of Kutter et al (abstract of EP 417637), and US 6001861 are discussed above. These references do not teach the intranasal administration of the dopamine agonist, pramipexole (although '861 teaches inhalation administration, it is not specify intranasal). WO 97/30977 teaches the use of a dopamine agonist in treating cocaine abuse/craving. It further teaches the intranasal route of administration of the effective agent (page 11, line 21). It would be obvious to one skilled in the art that pramipexole (a dopamine agonist) could be administered intranasally. Furthermore, a skilled artesian seeking a treatment for cocaine craving, would be motivated to combine the above cited art and use pramipexole through intranasal administration, particularly if they needed to administer the effective agent through a route other than oral or injection.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 15-30 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of US 6750235 B1.

The claims recite a method for treating a human with a stimulant (cocaine) dependency, which may involve craving, with the administration of pramipexole (a dopamine agonist), in a dose ranging from 1.5 mg/day to 6.0 mg/day, and an antidepressant or anticonvulsant (which may be lamotrigine).

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant invention claims 15-30 perform the same functions as the claims in '235, with the exception of the route of administration. '235 teach the intranasal administration of pramipexole wherein claims 15-30 of the instant invention do not. The specifications of the instant invention and '235 teach "*Oral administration is preferred*, but any other appropriate route of administration may be employed, for example, parenteral, intravenous, subcutaneous, intramuscular, intracranial, intraorbital, ophthalmic, intraventricular, intracapsular, intraspinal, intracisternal, intraperitoneal, *intranasal*, or aerosol administration." ('235 column 3, lines 51-57; instant invention page 6, lines 14-18). For one skilled in the art, especially since the applicant admits that oral administration is preferred, there would be ample motive, and it would clearly be obvious, to use the oral or other non-intranasal route of administration.

Conclusion

8. Claims 1-30 are rejected.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on M-F 7:30 A.M. - 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregg Polansky

VICKIE KIM
PRIMARY EXAMINER